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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,188	05/09/2001	Ilham Mohamed Saleh Saeed Abuljadayel	674528-2003.1	6161
20999 7590 12/24/2008 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL.. NEW YORK, NY 10151				
EXAMINER				
CANELLA, KAREN A				
ART UNIT		PAPER NUMBER		
1643				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/853,188

**Applicant(s)**ABULJADAYEL, ILHAM  
MOHAMED SALEH SAEED**Examiner**

Karen A. Canella

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 101 and 104-107 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-32 and 34-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.   |

Continuation of Disposition of Claims: Claims pending in the application are 1-3,5,7,11,13,15,17,19,20,22,23,25,26,28-32,34-41,101 and 104-107.

### DETAILED ACTION

Claims 1-3, 40 and 41 have been amended. Claims 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-32, 34-41, 101 and 104-107 are pending and under consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-3, 7, 17, 19, 20, 22, 23, 25, 26, 28, 29-32, 34-41 under 35 U.S.C. 102(b) as being anticipated by Gilford (U.S. 4,058,367) is maintained for reasons of record.

Claims 1, 2, 19, 20, 22, 23, 25, 26, 28, 29-32, 34-41 are drawn to a device comprising a chamber, means for introducing into said chamber a cell population, means for introducing into said chamber an agent, incubation means and mixing means. Claim 3 embodies the device of claim 1 further comprising means for conducting cell counts; transfer means, temperature control means, mixing means and removal means. Claim 7 embodies the device of claim 3 wherein the means for conducting cell counts is a cytometer. Claim 17 embodies the device of claim 3 including a microprocessor.

It is noted that means for introducing into said chamber an agent capable of increasing the relative number of undifferentiated cells in a cell population is not given patentable weight because it refers only to the intended use of the agent. Section 2106 of the MPEP states

*Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.*

Thus, the intended use of device, wherein the agents are limited to the antibody which binds to MHC antigens, erythropoietin or GM-CSF has not been given patentable weight

It is further noted that noted that the recitation of a device for forming and/or increasing the relative number of undifferentiated cells in a cell population comprising hematopoietic cells

has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Gilford et al discloses a device comprising a chamber for blood (abstract, 4<sup>th</sup> paragraph), means for introducing an agent into said blood, incubation means (column 5, lines 8-10), , mixing means (column 8, lines 67-68) and a microprocessor means (column 5, lines 32-54), as well as a cell counting and sizing apparatus (column 1, lines 67-68) which fulfills the requirement of claim 7 requiring a cytometer. .

Given that the device of the prior art comprises the same structural elements as claimed in the instant device, the claimed device is anticipated because the prior art device will inherently have all the functional characterizes of the claimed device . See *Ex parte Novitski* 26 USPQ 1389 (BPAI 1993).

The rejection of claims 1-3, 7, 17, 19, 20, 22, 23, 25, 26, 28, 29-32, 34-41 under 35 U.S.C. 102(b) as being anticipated by Tomioka et al (U.S. 4,983,359) is maintained for reasons of record..

Tomioka et al disclose a device comprising an incubator, mixing means, a flow cytometer and a data processing means, said data processing means fulfilling the specific requirement of the microprocessor of claim 17 (claims 1 and 2 of '359). Tomioka et al disclose a transfer means for blood cells which is a syringe coupled to a pipette (column 4, lines 4-7). Tomioka et al disclose a transfer means for a monoclonal antibody which is a syringe coupled to a pipette (column 4, lines 24-35).

Given that the device of the prior art comprises the same structural elements as claimed in the instant device, the claimed device is anticipated because the prior art device will inherently have all the functional characterizes of the claimed device . See *Ex parte Novitski* 26 USPQ 1389 (BPAI 1993).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1-3, 5, 7, 17, 19, 20, 22, 23, 25, 26, 28, 29-32, 34-41 under 35 U.S.C. 103(a) as being unpatentable over Gilford (U.S. 4,058,367) in view of what is well known in the art as evidenced by North (2001/0052763) is maintained for reasons of record...

Claim 5 embodies the device of claim 3 wherein the means for conducting cell counts is a coulter counter.

Gilford et al teaches said device with a cell counter, but does not specifically disclose a Coulter Counter.

Use of a Coulter Counter as a specific cell counter is well known in the art as exemplified by North, who teaches that the Coulter counter is particle counter useful for blood cell counting and invented in 1953 (paragraph [003]).

It would have been prima facie obvious at the time the claimed invention was made to use a Coulter Counter as a cell counter as part of the device of Gilford. One of skill in the art would have been motivated to do so because the Coulter Counter is well known as a means for counting blood cells as exemplified by North.

The rejection of claims 1-3, 7, 11, 13, 17, 19, 20, 22, 23, 25, 26, 28, 29-32, 34-41 under 35 U.S.C. 103(a) as being unpatentable over Tomioka et al (U.S. 4,983,359) in view of Johnson et al (U.S. 4,563,907) is maintained for reasons of record...

Claims 11 and 13 embody the device of claim 3 wherein the transfer means is a syringe driven by a motor.

Tomioka et al teaches a syringe which operates a pipette as a transfer means. Tomioka et al do not specifically state that said syringe is a motor driven syringe.

Johnson et al teach a motor driven syringe for controlling a pipette (column 4, first paragraph). Johnson et al teach that the improvement associated with the use thereof being the elimination of operator interaction for the specification of the quantity of material to be transferred (abstract).

It would have been prima facie obvious at the time the claimed invention was made to use a motor driven syringe in the device of Tomioka et al. One of skill in the art would have been motivated to do so by the teachings of Johnson et al on the improvement associated with the use thereof being the elimination of operator interaction for the specification of the quantity of material to be transferred (abstract).

Applicant argues that Gilford relates to an apparatus for processing fluids for ascertaining physical and or chemical properties of the fluids but does not teach or even suggest an apparatus that comprises an agent selected from an antibody, erythropoietin or GM-CSF. Applicant argues that Tomioka et al relates to an apparatus for measuring lymphocyte subclasses, but that Tomioka et al does not teach or suggest an agent selected from an antibody that binds to MHC antigens, erythropoietin or GM-CSF. This has been considered but not found persuasive. The instant claims require components of an apparatus, but do not require an antibody, erythropoietin or GM-CSF. Applicant argues against the rejections under 35 U.S.C. 103(a) against stating that the combinations of references do not teach or suggest an antibody that binds to an MHC antigen, erythropoietin or GM-CSF. This is not found persuasive for the reason states above, namely, that the instant claims require an apparatus made of component parts. The instant claims do not require an antibody that binds to MHC, erythropoietin or GM-CSF.

Claims 101 and 104-107 are free of the art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643